I, Roy VREELAND, a Fellow of the Institute of Linguists, and a Fellow of the Institute of Translation and Interpreting, of Forrester Ketley & Co., of Forrester House, 52 Bounds Green Road, London, N11 2EY, do hereby certify that I am a professional full-time translator well acquainted with the English and German languages and that to the best of my knowledge and belief the following is a true translation into the English language of the claims annexed to the International Preliminary Examination Report relating to International Patent Application number PCT/DE2003/002799.

R. Vreeland

Roy VREELAND

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Claims

1. A process for the production of biodegradable polymer particles which comprises:

   a) introduction of at least one inducible gene into a microorganism, wherein the gene codes for a protein which controls the size of the polymer particles and is selected from the group which comprises the phasin gene phaP from *Ralstonia eutropha* and the phasin gene phaF from *Pseudomonas oleovorans*;

   b) introduction of at least one further gene which codes for a protein involved in the formation of the polymer particles;

   wherein at least one of the genes introduced into the microorganism in a) and b) comprises a polymer particle binding domain and at least one binding domain, wherein the at least one binding domain is capable of binding a biologically active substance and/or a coupling reagent; and

   c) cultivation of the microorganism with induction of the at least one inducible gene stated in a) in a culture medium under conditions which are suitable for the production of the biodegradable polymer particles by the microorganism.

2. A process according to claim 1, wherein the at least one further gene which codes for a protein involved in the formation of the polymer particles codes for a thiolase, a reductase or a polymer synthase.

3. A process according to claim 2, wherein the at least one further gene which codes for a protein involved in the formation of the polymer particles codes for phaA thiolase, phaB ketoacyl reductase or phaC synthase from *Ralstonia eutropha*.

4. A process according to any one of the preceding claims, wherein at least one additional gene which codes for a thiolase and/or a polymer synthase is introduced into the cell.

5. A process according to any one of the preceding claims, wherein at least one fatty acid with functional side groups and particularly preferably at least one hydroxy fatty acid and/or at least one mercapto fatty acid and/or at least one β-amino fatty acid is introduced into the culture medium as a substrate for the formation of the polymer particles.

6. A process according to any one of the preceding claims, wherein the substrate is added to the culture medium in such a quantity that it is sufficient to ensure control of the size of the polymer particles.

7. A process according to any one of the preceding claims, wherein the microorganism used is selected from the genera comprising *Ralstonia*, *Alcaligenes*, *Pseudomonas* and *Halobiforma*.

8. A process according to claim 7, wherein the microorganism used is selected from the group comprising *Ralstonia eutropha*, *Alcaligenes latus*, *Escherichia coli*, *Pseudomonas fragi*, *Pseudomonas putida*, *Pseudomonas oleovorans*, *Pseudomonas aeruginosa*, *Pseudomonas fluorescens*, and *Halobiforma haloterrestris*.

9. A process according to any one of the preceding claims, wherein the cultivated microorganisms are disrupted in per se known manner and the polymer particles then separated from the cell debris.

10. A process according to claim 9, wherein a lipid layer located on the surface of the polymer particles is separated from the polymer particles

obtained according to the process of claim 9 and replaced by a lipid layer of another composition.

11. A process according to any one of the preceding claims, wherein particle size is controlled by the at least one inducible gene in such a manner that the polymer particles formed have a diameter of 10 nm to 3 µm, preferably a diameter of 10 nm to 900 nm, and particularly preferably a diameter of 10 nm to 100 nm.

12. A process according to any one of the preceding claims, wherein the polymer particle binding domain comprises part of a protein bound to the surface of the polymer particle, wherein the protein is selected from the group comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-controlling protein.

13. A process according to any one of the preceding claims, wherein the at least one binding domain which is capable of binding a biologically active substance and/or a coupling reagent is selected from the group comprising oligopeptides, enzymes, abzymes or non-catalytic proteins.

14. A process for the *in vitro* production of biodegradable polymer particles consisting of polyhydroxyalkyl carboxylates which comprises:

a) provision of a solution suited to polymer particle formation with at least one substrate;

b) introduction into the solution of a protein which is suited to controlling the size of the polymer particles; and

c) introduction of at least one further protein which is involved in the formation of the polymer particles,

wherein at least one of the proteins introduced in stage b) and/or c) is selected such that it comprises a polymer particle binding domain and at least one binding domain, wherein the at least one binding domain is

capable of binding a biologically active substance and/or a coupling reagent.

15. A process according to claim 14, wherein at least one fatty acid and an acyl CoA oxidase is added to the solution suited to polymer particle formation in stage a).

16. A process according to any one of claims 14 or 15, wherein, in stage a), at least one substrate is added to the solution suited to polymer particle formation in such a quantity that it is sufficient to ensure control of the size of the polymer particles.

17. A process according to any one of claims 14 to 16, wherein, in stage b), a polymer particle size-controlling protein is introduced which is derived from the family of phasin-like proteins.

18. A process according to claim 17, wherein, in stage b), a polymer particle size-controlling protein is introduced which is selected from the group comprising the phasin from *Ralstonia eutropha* and the phasin from *Pseudomonas oleovorans*.

19. A process according to any one of claims 14 to 18, wherein the at least one further protein involved in polymer particle formation used in stage c) is a polymer synthase.

20. A process according to claim 19, wherein the at least one further protein involved in polymer particle formation used in stage c) is a polymer synthase which is selected from the group comprising the polymer synthase from *R. eutropha*, *P. oleovorans*, *P. putida* and *P. aeruginosa*.

21. A process according to claim 19 or claim 20, wherein the polymer synthase is added to the solution in such a quantity that it is sufficient to ensure control of the size of the polymer particles.

22. A process according to any one of claims 14 to 21, wherein, in stage a), at least one pharmaceutically active substance is added to the solution.

23. A process according to any one of claims 14 to 22, wherein, in order to control the composition of the lipid layer on the surface of the polymer particle, at least one amphiphilic molecule from the group of phospholipids and ether lipids is added to the solution from step a).

24. A process according to any one of claims 14 to 23, wherein the polymer particle binding domain is part of the protein bound to the surface of the polymer particle, wherein the protein is selected from the group which comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-controlling protein.

25. A process according to any one of claims 14 to 24, wherein the at least one binding domain which is capable of binding a biologically active substance and/or a coupling reagent is selected from the group comprising oligopeptides, enzymes, abzymes or non-catalytic proteins.

26. A polymer particle of polyhydroxyalkyl carboxylates of defined size, with a surface layer of amphiphilic molecules, into which [is introduced] at least one protein which is selected from the group comprising a polymer depolymerase, a polymer regulator, a polymer synthase and a particle size-influencing protein, wherein the at least one protein comprises a polymer particle binding domain and a binding domain which is capable of binding a biologically active substance and/or a coupling reagent.

27. A polymer particle according to claim 26, produced according to a process described in claims 1 to 25.

28. Use of the polymer particles according to any one of claims 26 or 27 for the production a pharmaceutical preparation, a pesticide or a herbicide.

29. Use according to claim 28, wherein the pharmaceutical preparation is suitable for the treatment of diseases of the central nervous system.